



General

Guideline Title

Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN.

Bibliographic Source(s)

Tabbers MM, DiLorenzo C, Berger MY, Faure C, Langendam MW, Nurko S, Staiano A, Vandenplas Y, Benninga MA. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. J Pediatr Gastroenterol Nutr. 2014 Feb;58(2):258-74. PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Constipation Guideline Committee of the North American Society for Pediatric Gastroenterology. Evaluation and treatment of constipation in infants and children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr. 2006 Sep;43(3):e1-13. [96 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the quality of evidence for therapeutic interventions (High, Moderate, Low, Very Low) for questions 5-9 are provided at the end of the "Major Recommendations" field.

Question 1: What Is the Definition of Functional Constipation?

Based on expert opinion, the guideline committee recommends the Rome III criteria for the definition of functional constipation for all age groups (see Table 2 in original guideline document).

Based on expert opinion, the diagnosis of functional constipation is based on history and physical examination.

Question 2: What Are the Alarm Signs and Symptoms That Suggest the Presence of an Underlying Disease Causing the Constipation?

Based on expert opinion, the guideline committee recommends using Tables 3, 4, and 5 in the original guideline document for alarm signs and symptoms and diagnostic clues to identify an underlying disease responsible for the constipation.

Question 3: In the Diagnosis of Functional Constipation in Children, What Is the Diagnostic Value of Digital Rectal Examination, Abdominal

Radiography, Colonic Transit Time and Transabdominal Rectal Ultrasonography?

Based on expert opinion, if only 1 of the Rome III criteria is present and the diagnosis of functional constipation is uncertain, a digital examination of the anorectum is recommended.

Based on expert opinion, in the presence of alarm signs or symptoms or in patients with intractable constipation, a digital examination of the anorectum is recommended to exclude underlying medical conditions.

The routine use of an abdominal radiograph to diagnose functional constipation is not indicated.

Based on expert opinion, plain abdominal radiography may be used in a child in whom fecal impaction is suspected but in whom physical examination is unreliable/not possible.

Colonic transit studies are not recommended to diagnose functional constipation.

Based on expert opinion, a colonic transit study may be useful to discriminate between functional constipation and functional nonretentive fecal incontinence and in situations in which the diagnosis is not clear.

Rectal ultrasound is not recommended to diagnose functional constipation.

Question 4: Which of the Following Diagnostic Tests Should Be Performed in Children with Constipation to Diagnose an Underlying Disease?

Routine allergy testing is not recommended to diagnose cow's-milk allergy in children with functional constipation.

Based on expert opinion, a 2- to 4-week trial of avoidance of cow's-milk protein (CMP) may be indicated in the child with intractable constipation.

Based on expert opinion, the guideline committee does not recommend routine laboratory testing for hypothyroidism, celiac disease, and hypercalcemia in children with constipation in the absence of alarm symptoms.

Based on expert opinion, the main indication to perform anorectal manometry (ARM) in the evaluation of intractable constipation is to assess the presence of the rectoanal-inhibitory reflex (RAIR).

Rectal biopsy is the gold standard for diagnosing Hirschsprung disease (HD).

Based on expert opinion, the guideline committee does not recommend performing barium enema as an initial diagnostic tool for the evaluation of children with constipation.

Question 5: Which of the Following Examinations Should Be Performed in Children with Intractable Constipation to Evaluate Pathophysiology and Diagnose an Underlying Abnormality?

Based on expert opinion, colonic manometry may be indicated in patients with intractable constipation before considering surgical intervention.

The routine use of magnetic resonance imaging (MRI) of the spine is not recommended in patients with intractable constipation without other neurologic abnormalities.

Based on expert opinion, the guideline committee does not recommend obtaining full-thickness colonic biopsies to diagnose colonic neuromuscular disorders in children with intractable constipation.

Based on expert opinion, the guideline committee does not recommend routine use of colonic scintigraphy studies in children with intractable constipation.

Question 6: What Is the Additional Effect of the Following Nonpharmacologic Treatments in Children with Functional Constipation?

A normal fiber intake is recommended in children with constipation. (Very Low)

Based on expert opinion, the guideline committee recommends a normal fluid intake in children with constipation. (Low)

Based on expert opinion, the guideline committee recommends a normal physical activity in children with constipation. (Low)

The routine use of prebiotics is not recommended in the treatment of childhood constipation. (Very Low)

The routine use of probiotics is not recommended in the treatment of childhood constipation. (Low)

The routine use of an intensive behavioral protocolized therapy program in addition to conventional treatment is not recommended in childhood constipation. (Low)

Based on expert opinion, the guideline committee recommends demystification, explanation, and guidance for toilet training (in children with a developmental age of at least 4 years) in the treatment of childhood constipation. (Low)

The use of biofeedback as additional treatment is not recommended in childhood constipation. (Low)

Based on expert opinion, the guideline committee does not recommend the routine use of multidisciplinary treatment in childhood constipation. (Low)

Based on expert opinion, the guideline committee does not recommend the use of alternative treatments in childhood constipation. (Low)

Question 7: What Is the Most Effective and Safest Pharmacologic Treatment in Children with Functional Constipation?

The use of polyethylene glycol (PEG) with or without electrolytes orally 1 to 1.5 g \cdot kg⁻¹ · day⁻¹ for 3 to 6 days is recommended as the first-line treatment for children presenting with fecal impaction. (Very Low)

An enema once per day for 3 to 6 days is recommended for children with fecal impaction, if PEG is not available. (Very Low)

The use of PEG with or without electrolytes is recommended as the first-line maintenance treatment. A starting dose of $0.4~g\cdot kg^{-1}\cdot day^{-1}$ is recommended and the dose should be adjusted according to the clinical response. (Very Low)

The addition of enemas to the chronic use of PEG is not recommended in children with constipation. (Very Low)

The use of lactulose as the first-line maintenance treatment is recommended, if PEG is not available. (Very Low)

Based on expert opinion, the use of milk of magnesia, mineral oil, and stimulant laxatives may be considered as an additional or second-line treatment. (Very Low)

Based on expert opinion, maintenance treatment should continue for at least 2 months. All symptoms of constipation symptoms should be resolved for at least 1 month before discontinuation of treatment. Treatment should be decreased gradually. (Low)

Based on expert opinion, in the developmental stage of toilet training, medication should only be stopped once toilet training is achieved. (Low)

Question 8: What Is the Efficacy and Safety of Novel Therapies for Children with Intractable Constipation?

Based on expert opinion, the guideline committee does not recommend the routine use of lubiprostone, linaclotide, and prucalopride in children with intractable constipation. (Low)

Based on expert opinion, the guideline committee recommends antegrade enemas in the treatment of selected children with intractable constipation. (Low)

The routine use of transcutaneous nerve stimulation (TNS) in children with intractable constipation is not recommended. (Very Low)

Question 9: What Is the Prognosis and What Are Prognostic Factors in Children with Functional Constipation?

See Table 7 in the original guideline document. See also the Appendix for more details (see the "Availability of Companion Documents" field).

Definitions:

Quality of Evidence for Therapeutic Interventions

High: Further research is unlikely to change our confidence in the estimate of effect.

Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Very low: Any estimate of effect is uncertain.

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document:

- Algorithm for the evaluation and treatment of infants <6 months of age
- Algorithm for the evaluation and treatment of infants ≥6 months of age

Scope

Disease/Condition(s)

- Functional constipation
- Hirschsprung disease (HD)
- Intractable constipation

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Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Pediatrics

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide recommendations for the diagnostic evaluation of children presenting with constipation and the treatment of children with functional constipation
- To assist medical care providers in the evaluation and management of children with functional constipation

Target Population

Infants and children with constipation

Interventions and Practices Considered

Diagnosis/Evaluation

- 1. Use of the Rome III diagnostic criteria
- 2. Assessment for alarm signs and symptoms
- 3. Digital rectal examination
- 4. Plain abdominal radiography
- 5. Colonic transit study
- 6. Trial avoidance of cow's-milk protein (CMP)
- 7. Anorectal manometry (ARM) or rectal suction biopsy (to diagnose Hirschsprung disease [HD])
- 8. Colonic manometry

Management/Treatment

- 1. Normal fluid and fiber intake
- 2. Normal physical activity
- 3. Parental guidance on toilet training
- 4. Polyethylene glycol (PEG) with or without electrolytes (first line treatment)
- 5. Enemas
- 6. Lactulose (first-line maintenance if PEG unavailable)
- 7. Milk of magnesia, mineral oil, stimulant laxatives (additional or second-line treatment)

Note: The following were considered but not recommended: rectal ultrasound; routine allergy testing for CMP; routine laboratory testing for hypothyroidism, celiac disease, and hypercalcemia; barium enema as an initial diagnostic tool; routine use of magnetic resonance imaging (MRI); full-thickness colonic biopsy; routine use of colonic scintigraphy; routine use of prebiotics or probiotics; routine use of intensive behavioral protocolized therapy in addition to conventional treatment; routine use of multidisciplinary treatment; alternative treatments; addition of enemas to chronic use of PEG; routine use of lubiprostone, linaclotide, and prucalopride; and routine use of transcutaneous nerve stimulation (TNS).

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Rate of symptomatic relief
- Prevention and control of symptoms
- Medication and treatment side effects
- Quality of life
- Bowel movement frequency

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic literature searches were performed by a clinical librarian from inception to October 2011. The EMBASE, MEDLINE, Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials, and PsycINFO databases were searched.

The inclusion criteria were as follows:

- Study population consisting of children of ages 0 to 18 years in whom functional constipation was diagnosed, treated, or its course followed.
 The key words used to describe constipation were "constipation," "bstipation," "faecal/fecal incontinence," "coprostasis," "encopresis," and "soiling." Excluded were the studies concerning children with organic causes of constipation and children with exclusively functional nonretentive fecal incontinence.
- 2. A clear definition of functional constipation had to be provided by the authors.
- 3. To evaluate the value of tests in diagnosing functional constipation (question 3), the committee included systematic reviews and original studies related to the diagnostic accuracy of the specific tests. The reference standard for functional constipation had to be defined by the authors in terms of findings at history and physical examination.
- 4. In studies evaluating the effects of treatments or interventions (questions 6, 7, and 8), the following inclusion criterion was used: systematic reviews of randomized controlled trials (RCTs) and/or RCTs containing at least 10 individuals per arm.
- 5. In studies evaluating the outcome of functional constipation (questions 4, 5, and 9), the following inclusion criteria were used: systematic reviews of prospective or retrospective controlled studies and original studies with a follow-up of at least 8 weeks.

An additional strategy to identify studies involved searching the reference lists of review articles and included studies. No language restriction was applied. Furthermore, all of the guideline members were asked to search the literature with respect to their assigned topics to possibly uncover further studies that may have been missed by the former search.

Number of Source Documents

The initial search for all questions revealed 3452 studies.

See detailed discussion in original guideline document for search yield and number of included studies for each question.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Therapeutic Interventions

High: Further research is unlikely to change confidence in the estimate of effect.

Moderate: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Very low: Any estimate of effect is uncertain.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The approach of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) was used to identify outcomes. A draft version was circulated, and every workgroup member was allowed to add outcomes. Group members were asked to rate relative importance of the outcomes on a 9-point scale: limited (1–3), important but not critical (4–6), or critical (7–9) for decision making. The workgroup members were also asked to discuss personal experience. Based on the answers of the guidelines group members and patient preferences from a focus group, 8 outcome measures were selected: pain during defecation, defecation ≥3 times per week, fecal incontinence frequency, difficulty with defecation, worsening constipation, quality of life, possible harm from laxatives (cancer, tolerance, adverse effects), and abdominal pain.

The levels and quality of evidence were ass	essed using the classification system of the Oxford Centre for Evidence-Based Medicine
(http://www.cebm.net) (diagnostic and prognostic questions) and the GRADE system (therapeutic questions) and are

summarized in the online-only appendix (http://links.lww.com/MPG/A295). Grades of evidence for each statement are based on the grading of the literature. If no therapeutic studies were found, we decided to define the quality of evidence as "low."

Using the GRADE system, the quality of evidence for therapeutic interventions (questions 5, 6, and 9) was graded as shown in the "Rating Scheme for the Strength of the Evidence" field.

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

The project started in September 2011 by formulating 9 clinical questions (see Table 1 in the original guideline document). Seven questions were chosen based on the Dutch guidelines for functional constipation. In addition, 2 new questions were added to the present guidelines: questions 5 and 8. After the questions were formulated, the guidelines committee was subdivided into subgroups that dealt with each question separately. Questions 1 and 2 were answered based on expert opinions and earlier published guidelines. Questions 3 to 9 were answered using the results of systematic literature searches.

Consensus Meeting and Voting

Three consensus meetings were held to achieve consensus on and formulate all of the recommendations: September 2012, February 2013, and May 2013. Each subgroup presented the recommendations during the consensus meetings, wherein these were then discussed and modified according to the comments of the attendees. The consensus was formally achieved through nominal group technique, a structured quantitative method. The group anonymously voted on each recommendation. A 9-point scale was used (1=strongly disagree to 9=fully agree), and votes are reported by each recommendation. It was decided in advance that consensus was reached, if >75% of the working group members voted 6, 7, 8, or 9. The consensus was reached for all of the questions.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The final draft of the guidelines was sent to all of the committee members for approval in May 2013.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for some of the recommendations (see "Major Recommendations" field).

Expert opinion was used where no randomized controlled trials were available to support the recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate diagnosis and treatment of functional constipation in infants and children

Potential Harms

- Possible harms from laxatives (cancer, tolerance, adverse effects) and abdominal pain
- High-dose polyethylene glycol (PEG) given orally is associated with a higher frequency of fecal incontinence during treatment of the fecal impaction compared with enema use.
- Potential complications of antegrade continence enemas (ACE) include development of granulation tissue, leakage around the tube, tube
 dislodgment, skin infection, and stoma stenosis and should be thoroughly considered and discussed with parents and children.

Qualifying Statements

Qualifying Statements

The present guideline provides recommendations for the diagnostic evaluation of children presenting with constipation and the treatment of children with functional constipation. It is intended to serve as a general guideline and should not be considered a substitute for clinical judgment or used as a protocol applicable to all patients. The guideline is also not aimed at the management of patients with underlying medical conditions causing constipation, but rather just for functional constipation.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Tabbers MM, DiLorenzo C, Berger MY, Faure C, Langendam MW, Nurko S, Staiano A, Vandenplas Y, Benninga MA. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. J Pediatr Gastroenterol Nutr. 2014 Feb;58(2):258-74. PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 Nov (revised 2014 Feb)

Guideline Developer(s)

European Society for Pediatric Gastroenterology, Hepatology, and Nutrition - Professional Association

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition - Professional Association

Source(s) of Funding

Guideline development was financially supported by North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). No other support was received from industry.

Guideline Committee

Guidelines Committee

Composition of Group That Authored the Guideline

Committee Members: M.M. Tabbers, C. DiLorenzo, M.Y. Berger, C. Faure, M.W. Langendam, S. Nurko, A. Staiano, Y. Vandenplas, and M.A. Benninga

Financial Disclosures/Conflicts of Interest

C.D.L. is a consultant for Janssen, Sucampo, AstraZeneca, and Ironwood. C.F. is a consultant for Sucampo. S.N. is a consultant for Janssen and Sucampo. A.S. is a consultant for Valeas and DMG Italy. Y.V. is a consultant for Biocodex and United Pharmaceuticals. M.Y.B. is a consultant for Shire and Sucampo. The other authors report no conflicts of interest.

Guideline Status

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This guideline meets NGC's 2013 (revised) inclusion criteria.

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Elec	tronic copies: Available f	from the North American Society	for Pediatric Gastroen	terology, Hepatology, an	d Nutrition (NASPO	GHAN) Web
site						

Print copies: Available from the Executive Director, NASPGHAN, P.O. Box 6, Flourtown, PA 19031; E-mail: naspghan@naspghan.org.

Availability of Companion Documents

The following are available:

- Evidence tables as an online appendix from the Journal of Pediatric Gastroenterology and Nutrition Web site
- Continuing medical education (CME) activity from the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) Web site

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on June 9, 2003. The information was verified by the guideline developer on June 16, 2003. This NGC summary was updated by ECRI on November 14, 2006. This NGC summary was updated by ECRI Institute on April 21, 2015. The information was verified by the guideline developer on May 1, 2015.

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